

Section 1: Identification

Product Name	Fluoxetine Hydrochloride USP		
Commercial Name	Prozac, Sarafem, Fontex, Adzac, Alvenin, Branfluoxe, Nuzac, Lovan, Lonparin, Levilin, Ladose, Foncin, Flutin, Zolovan, :		
Product Use	Restricted use as an active ingredient in pharmaceutical industry.		
Restrictions On Use	Not available		
Product Code	30-3409		
Company	PCCA	In case of emergency contact:	
	9901 South Wilcrest	CHEMTREC (24hr) 1-800-424-9300	
	Houston, TX 77099		
	Phone: 1-800-331-2498		
	Fax: 1-800-874-5760		

Section 2: Hazard(s) Identification

OSHA Haz Com:	Acute toxicity, Oral (Category 3) Acute toxicity, Inhalation. (Category 3) Skin irritation (Category 2) Eye
CFR 1910.1200	Damage (Category 1) Aquatic Chronic (Category 1)
Signal Word	DANGER

Hazard Statement(s) Toxic if swallowed. Toxic if inhaled. Causes serious eye damage. Causes skin irritation. Very toxic to aquatic life with long lasting effects.

Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention	P260 Do not breathe dust P264 Wash thoroughly after handling P273 Avoid release to the environment.
Response	P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+ P351+ P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing P310 Immediately call a POISON CENTER or doctor/physician. P330 Rinse mouth P391 Collect spillage
Storage	P405: Store locked up
Disposal	P501: Dispose of contents/container in a site approved for chemical and hazardous waste or burned in a specialised burning centre

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Fluoxetine HCL
% By Weight	100
CAS#	56296-78-7
Molecular Weight	345.82 g/mole
Chemical Formula	C17H18F3NO.HCl
Synonym(s)	(+)-Methyl-gamma-(4-(trifluoromethyl)phenoxy)benzenepropanamine hydrochloride

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Fluoxetine Hydrochloride	59333-67-4	98-101.5%		

Section 4: First-Aid Measures

Inhalation	Allow the victim to rest in a well ventilated area. Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. In severe cases or if symptoms persists, seek medical attention
Skin Contact	After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.
Eye Contact	Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention
Ingestion	Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention
Symptoms/Effects	
Acute	Not available
Delayed	Not available.
Immediate Medical Attention	Not available.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

In case of fire use water, chemical type foam, carbon dioxide, dry chemical. Prevent run off of water from entering drains

Unsuitable Extinguishing Media

Not available.

Products of Combustion

CO, CO₂, NO_x, HCl, HF

Firefighters Special Equipment and Precautions

Wear: -Gas masks scuba -Complete protective equipment composed by: helmet whit face shield and neck protection, fireproof jacket and trousers with straps around arms, legs and waist.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep away any ignition source. Wear protective equipment. Keep unprotected persons away. Use respiratory protective device against the effects of fumes. Ensure adequate ventilation. Methods and materials for containment and cleaning up: Absorb spillage in earth or sand. Sweep or shovel-up spillage and remove to a safe place. Damp down to avoid dust generation. Environmental precautions: Do not allow to penetrate the ground/soil. Prevent seepage into sewage system, workpits and cellars. Inform respective authorities in case of seepage into water course or sewage system.

Section 7: Handling and Storage

Handling: This product should be handled only by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals, who should take into account the fire, health and chemical hazard data given on this sheet. It should always be handled in an efficient fume hood or equivalent system and, if necessary, wear protective equipment. Care should be taken to prevent the chemical from coming into contact with the skin or eyes and from contaminating personal clothing. Storage: Avoid contact with oxidising substances For safety purposes, the substance does not require any special storage conditions. As an indication, the information provided by official monographs are: USP: Preserve in tight containers. EP: Preserve in the original packaging tightly closed For storage of the substance for pharmaceutical use, or for registration purposes please refer to the stability data conducted in-house and reported in the document regulatory "Active Substance Master File" (ASMF or DMF).

Section 8: Exposure Controls/Personal Protection

Exposure Limits Not available.

Engineering Controls

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes and clothing.

Personal Protection

Eye/face protection: Tightly fitting safety goggles. Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Hand protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Skin and body protection: The type of protective equipment (es. Tyvek suit) must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Complete suit protecting against chemicals, flame retardant antistatic protective clothing. Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) with cartridges P1 (inert substances) P2 (harmful substances) P3 (toxic substances). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	crystalline powder, white to almost white		
Odor	Odorless		
Odor Threshold	Not available		
Melting Point	above 200 °C with decompos	pH	Not available.
Freezing Point	Not available	Vapor Pressure	Not available.
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	Not available	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Dissociation constant (pKa):	Evaporation Rate	Not available
Flash Point	Not available.	Autoignition temperature	Not available
Flammability	Not availble	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	sparsingly soluble in water		
Other	Decomposition temperature above 200 °C		

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	The product is stable in usual working conditions
Hazardous Polymerization	Not available.
Conditions to Avoid	Excess heat. flames and sparks
Incompatible Materials	Strong oxidising agents. Alkali metals, bases, strong acids, halogens
Hazardous Decomposition Products	The substance evolves toxic fumes due to the presence of CO, CO ₂ , NO _x , HCl, HF

Section 11: Toxicological Information

RTECS	UI4050000
Acute Toxicity	
Acute toxicity	Information from ChemIDplus Acute Oral LD 50 rat mg/kg 452 Acute Oral LD 50 mouse mg/kg 248
Skin Corrosion/Irritation	
No data available	
Serious Eye Damage/Irritation	
No data available	
Respiratory or Skin Sensitization	
Toxic if inhaled	
Germ Cell Mutagenicity	
No data available	
Carcinogenicity	
No data available	
Reproductive Toxicity	
No data available	
Routes of Entry	
Eye.	
Symptoms Related to Exposure	
No data available	

Potential Health Effects

Toxic if swallowed. May cause skin irritation

Target Organ(s) No data available**Section 12: Ecological Information****Ecotoxicity**

LC50 (Rainbow trout, 96h): 1.57 mg/l. EC50 (Daphnia magna, 48h): 0.94 mg/l Moderately toxic to fish and highly toxic to invertebrates and green algae.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Low potential to bioaccumulate in aquatic organisms. Can be considered persistent due to low rates of biodegradation and hydrolysis. No volatility expected.

Mobility in Soil

Not available

Other Adverse Effects

Not available

Section 13: Disposal Considerations**Waste Disposal**

Do not empty into drains. Use appropriate containment to avoid environmental contamination. Disposal should be in accordance with local, state or national regulation.

Disposal of Container

The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products.

Other Considerations

Not available

Section 14: Transport Information**DOT Classification**

UN number ADR/RID: 2811 IMDG: 2811 IATA: 2811 UN proper shipping name ADR/RID Toxic solid, organic, n.o.s. (Fluoxetine Hydrochloride) IMDG Toxic solid, organic, n.o.s. (Fluoxetine Hydrochloride) IATA Toxic solid, organic, n.o.s. (Fluoxetine Hydrochloride) Transport hazard class(es) ADR/RID: 6.1 IMDG: 6.1 IATA: 6.1 Packaging group ADR/RID: III IMDG: III IATA: III Environmental hazards ADR/RID: yes IMDG: marine pollutant IATA: yes

Section 15: Regulatory Information**Regulations**

Safety, health and environmental regulations/legislation specific for the substance no data available REACH exempted as API (Active Pharmaceutical Ingredient) CLP notified with submission VV871764-86 02-2119456121-51-0000

Other

Not available

Section 16: Other Information

Not available